

Ser. No. 09/743,895  
Response dated December 18, 2003  
Reply to Office action of June 18, 2003

### **REMARKS/ARGUMENTS**

This is in response to the office action dated June 18, 2003. A request for continued examination (RCE), a petition for a three month extension of time and appropriate fee accompany this response. Detailed comments regarding the objections/rejections made in the action are presented below.

### **SPECIFICATION**

In the action, an objection was made regarding the absence of continuation data in the first paragraph. However, this objection was addressed in applicants' last response. Specifically, applicants amended the specification to recite that the present application is a Section 371 national stage filing of PCT/US00/13118, which claims priority to U.S. provisional applications 60/134,331 and 60/134,572.

In the action, it was requested that a copy of the abstract be provided because the abstract from the PCT application is missing from the file. In response, applicant provides a copy of the abstract as was filed in the PCT application.

### **CLAIM OBJECTIONS**

In the action, claims 11-17, 20-21 and 34-37 were objected to because their dependency on cancelled claims. In response, applicant has amended claim 11 to depend from claim 2. The subject matter of claims 8 and 10, cancelled in the last response have been reintroduced as new claims 50 and 51. Claims 13-14, 20-21 and 34 have been amended to depend from new claim 50.

### **CLAIM REJECTIONS - 35 U.S.C. §102**

#### **Claims 2-7, 9 and 11-24**

In the action, claims 2-7, 9 and 11-24 were rejected as anticipated by U.S. patent 6,007,544 (Kim). Claim 2 has been amended to further define that the proximal portion prior to implantation has a larger profile than the distal portion. Therefore, now the claim has been amended to specify the configuration of the device at a time prior to implantaion that is not disclosed in the Kim patent. The Kim patent now should not be

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considered to anticipate the claim.

As discussed in applicant's previous responses, FIG. 38B of the Kim patent, cited in the action, shows the shape memory alloy implant during delivery, not yet implanted, with one end of the implant exposed to the warm temperature of the body (and thus expanded) and the other end not yet exposed to the warm internal environment (thus remaining unexpanded). Prior to implantation, as shown in FIG 38A, the Kim implant is configured to have both its proximal and distal ends in the same, small profile configuration, equal to the center region. This pre-implanted configuration of Kim does not anticipate the pre-implanted configuration defined in amended claim 2 wherein the proximal portion is a larger profile than the distal portion.

Reconsideration of the rejection of claim 2 and all claims dependent thereon is requested in view of this amendment.

#### Claim 49

The rejection of claim 49 as anticipated by Hussein is traversed for the same reasons presented in the previous response. In particular, the passages of Hussein cited in the office action do not disclose the subject matter of claim 49. In particular, at col. 2, lines 47-48 of Hussein, it is only stated that one of the embodiments of the stent can be a flexible spring. At col. 3, lines 35-40, it is stated that the flexible stent has a coil body with an anchoring coil. However, the passage continues on to state that it is the anchoring coil that prevents detachment of the stent from the heart wall, not the flexibility of the spring implant as is recited in applicants' claim.

At page 7 of the current office action, in response to applicants' previous amendment and remarks, the examiner states that Hussein "discloses a device that diameter and spacing of individual coils may be varied using a thermally deformable material (col. 27, line 52 to col. 28, line 17), which the examiner is interpreting as having sufficient longitudinally flexibility to resist migratory forces applied to the surrounding tissue". Applicants point out that the passage cited in that discussion corresponds to the disclosure of the Kim patent, not Hussein, and thus the citation appears to be in error. Applicants maintain that Hussein does not disclose forming implants to have

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sufficient longitudinal flexibility to observe migratory forces applied by the surrounding tissue.

#### **Claim Rejections - 37 U.S.C. §103**

##### **Claim Rejections Based on Kim in View of Whelan**

Claims 25-29 depend indirectly from claim 2 which has been amended to overcome the Kim reference as discussed above. Furthermore, Whelan does not supplant Kim to provide a teaching of an implant having a proximal portion with a larger profile than the distal portion. Accordingly, reconsideration of the rejection of claims 25-29 based on Kim in view of Whelan is requested.

##### **Claim Rejections Based on Kim in View of Wijay**

Claims 30 and 34-37 stand rejected as obvious by Kim in view of Wijay. Claims 30 and 34 through 37 depend from claim 2. Claim 2 has been amended to overcome the Kim reference as discussed above. The Wijay patent fails to disclose an implant having a proximal portion with a larger profile than the distal portion. Accordingly, the combination of Kim and Wijay should not be considered to render obvious the rejected claims. Reconsideration of the rejection is requested.

##### **Claim Rejections Based on the Combination of Kim, Whelan and Hussein**

Claims 31-33 stand rejected in view of the combination of Kim, Whelan and Hussein. The claims are dependent on claim 2, which has been amended to overcome the Kim reference. Neither Whelan nor Hussein disclose an implant having a proximal portion with a larger profile than the distal portion as is required by the claims. Accordingly, the combination of Kim, Wijay and Hussein should not be considered to render claims 31-33 as obvious. Reconsideration of the rejection is requested.

##### **Claim Rejections Based on Hussein in view of U.S. Patent 5,466,242 (Mori)**

The rejection of claims 38-45 based on the combination of Hussein and Mori is traversed because the references are not properly combinable to arrive at the subject

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matter of claim 38. In the action, it was stated that it would have been obvious for one skilled in the art to incorporate the large profile of the proximal portion of Mori with the flexible spring implant of Hussein because Hussein discloses that the spring may take on a variety of shapes. However, what motivation would one have to modify Hussein to have an increased profile at the proximal end of the implant versus any other variety of shapes? Applicants contend that only the disclosure of the present application provides the impetus for creating an implant with such a configuration. The combination, therefore, suggests that impermissible hindsight reasoning was used in combining the references. It is improper to use the applicants' specification as a road map for assembling various pieces of prior art to arrive at the applicants' claims. Reconsideration of the rejection is requested.

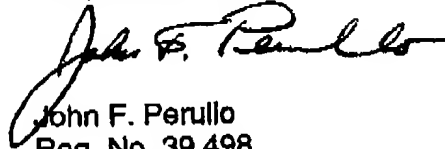
Rejections Based on the Combination of Hussein, Mori and Murphy-Chutorian

The rejection of claims 46-48 as obvious by the combination of Hussein, Mori and Murphy-Chutorian is traversed because the references are not properly combinable. Hussein is not properly combinable with Mori as discussed above. Additionally, Mori is not properly combinable with the Murphy-Chutorian patent. Murphy-Chutorian discusses placement of a stent inside of a coronary artery over channel holes that have been created to permit perfusion of blood into the myocardium. The patent suggests securing the stent in place by expanding it in the artery or by using surgical adhesive. One would not be motivated to apply the teaching of Mori to Murphy-Chutorian because mechanisms for securing the stent in place are already suggested by Murphy-Chutorian and increasing the size of one end of the stent as disclosed by Mori would appear to prevent the stent from aligning properly in the tubular artery. Reconsideration of the rejection of claims 46-48 is requested.

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Accordingly, in view of the foregoing amendments and explanatory remarks,  
applicants request reconsideration of the rejected claims.

Respectfully submitted,



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